

REMARKS/ARGUMENTS

Claims 19-38 stand rejected. In the present Amendment, claims 22, 27 and 32-36 have been amended. It is respectfully submitted that no new matter has been introduced into the present application by the amendments to the claims. Applicants respectfully request reconsideration of the present application in view of the amendments and following remarks.

Claims 20-22, 27 and 31-37 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Cardarelli et al. (U.S. Patent No. 4,400,374 – hereinafter sometimes referred to as the '374 patent) in view of Cardarelli et al. (U.S. Patent No. 3,590,119 – hereinafter sometimes referred to as the '119 patent). This rejection is respectfully traversed for the reasons set forth below.

The '374 patent teaches a composition for the controlled release of compounds to the environment from a dispenser made from a thermoplastic polymer, a thermoset polymer or mixtures thereof. The polymer of the '374 patent forms a matrix which contains the compounds to be released to the environment as well as a porosity inducing agent (i.e., a porosigen). The compounds are held in the porosity of the matrix and/or in the porosigens that are also held in the matrix. The compounds to be released to the environment are not dissolved in the polymer matrix itself. This is in stark contrast to the system described in the '119 patent, which uses a different type of polymer (i.e., an elastomer) to create the matrix. In the system of the '119 patent, the compounds to be released to the environment are dissolved in the polymer matrix itself. This is a required property of the elastomers that are suitable for use in the system of the '119 patent. One of ordinary skill in this art would not use the elastomers of the '119 patent in the composition of the '374 patent because the '374 patent teaches that the problem it is trying to solve is how to achieve controlled release of compounds to the environment using polymer

matrices in which the compounds are not soluble. In this regard, the '374 patent actually references the '119 patent and distinguishes the elastomers (i.e., "rubber" matrices) used therein, in which the compounds to be released must be soluble, from the thermoplastic or thermoset polymers ("plastic matrices") that form the matrix of the composition of the '374 patent, in which the compounds to be released are not soluble (see column 1, line 41 to column 2, line 3). To solve the problem of the compounds not being soluble in the plastic matrices, the composition of the '374 patent uses a porosity inducing agent which increases the porosity of the composition over time after the composition is contacted with water. This helps the compound to escape from the plastic matrices. Clearly, the teachings of the '374 patent would provide no motivation to one of ordinary skill in the art to use the elastomers of the '119 patent as the matrix material in the compositions of the '374 patent because the '374 patent teaches away from the use of such elastomers. Specifically, the problem that the invention of the '374 patent is trying to solve is how to create compositions that will release compounds to the environment in a controlled manner without using polymers in which the compounds will dissolve (e.g., the elastomers of the '119 patent). Accordingly, it is impossible for the '374 patent to provide the requisite motivation to use the elastomers of the '119 patent as the matrix material for the composition of the '374 patent since this would defeat the very purpose of the invention of the '374 patent. On this ground alone, it is respectfully submitted that the Examiner has not established a prima facie case of obviousness.

In addition to the above, it is respectfully submitted that the elastomers of the '119 patent are a different class of polymers than the thermoplastic polymers used in the present invention and in the '374 patent. Specifically, elastomers are rubbers which, by definition, are elastic at room temperature. In contrast, thermoplastics are brittle at room temperature. Further,

as discussed at length in the '374 patent, most of the compounds that are desirable for release to the environment are not soluble in thermoplastics but are soluble in elastomers. These fundamental differences in properties between the elastomers and the thermoplastics do not support the Examiner's position that a person of ordinary skill in the art would substitute one for the other.

Another problem with the Examiner's combination of the '119 patent with the '374 patent is that a person of skill in this art would not have a reasonable expectation that the combination would work for its intended purpose. Specifically, since the properties of the elastomers of the '119 patent are very different than the properties of the thermoplastic or thermoset polymers of the '374 patent, as discussed in the '374 patent itself, why would there be any expectation of success? The composition of the '374 patent is specifically designed to function with a polymer matrix in which the compounds to be released do not dissolve. The '374 patent itself teaches that it is "well known" that "agents not soluble within a polymeric matrix will not move at an efficacious rate through said matrix to said matrix surface and thus enter the ambient environment" (column 1, lines 62-65). Therefore, the components of the '374 composition have been selected so that the movement of the compound from the matrix to the ambient environment will be increased. If the polymer matrix of the '119 patent, in which the compounds would be soluble and have a much greater freedom of movement, was used as the matrix in the composition of the '374 patent, the compounds would most likely be released from the composition too fast, thereby defeating the purpose of the invention of the '374 patent. Specifically, the release from the '119 patent type of matrix is dependent on a diffusion-dissolution mechanism and is thus affected by the surface area of the matrix that is exposed to the environment. The porosigens in the '374 type of matrix would increase the surface area of

the matrix that is in contact with the environment and thus the combination of the '119 patent type of matrix with the composition of the '374 patent would most likely result in a much more rapid release of the compounds to the environment. Thus, there is no reasonable expectation that the suggested combination will successfully achieve the purpose of the invention and without that reasonable expectation of success, there can be no prima facie case of obviousness.

Finally, even assuming *arguendo* that: (1) one of ordinary skill in the art would somehow find motivation to combine the teachings of the '119 patent with the teachings of the '374 patent in the manner proposed by the Examiner, and (2) the said artisan would somehow have a reasonable expectation of success, both of which applicants strongly disagree with, there is still no prima facie case of obviousness because the Examiner has admitted that the combination of the '119 patent and the '374 patent does not teach all of the limitations of the present claims. Specifically, the Examiner has acknowledged that the '374 patent does not teach a polymer matrix that is a norbornene-ethylene copolymer and/or tetracyclododecene-ethylene copolymer. It is the Examiner's position that the closest matrix polymer taught in the '119 patent is a terpolymer of: (1) ethylene, (2) propylene and (3) ethylene norbornene (column 5, lines 56-68). The Examiner's combination would result in the terpolymer of the '119 patent being substituted for the polymer matrix of the '374 patent. However, that still does not result in a composition wherein the polymer matrix is a norbornene-ethylene copolymer and/or tetracyclododecene-ethylene copolymer, which is a required element of all of the claims of the present application. Accordingly, it is impossible for the combination of the '119 patent and the '374 patent to teach or suggest all of the limitations of the present claims, since neither patent contains any teaching or suggestion of the use of a norbornene-ethylene copolymer and/or tetracyclododecene-ethylene copolymer as the matrix material.

In the Examiner's response to applicants' previous arguments, the Examiner has stated that she is "unable to determine the unexpected and/or unusual results between the claimed rubber, norbornene-ethylene copolymer and propylene and ethylene norbornene taught by Cardarelli '119", and that therefore, "the burden is shifted to applicant to provide data showing unexpected results.....". It is respectfully submitted that this position is clearly incorrect. It is an axiom of patent law that the burden does not shift from the Examiner to the applicant until the Examiner has established a prima facie case of obviousness. As discussed above, the Examiner has not and cannot establish a prima facie case of obviousness based on the '119 and '374 patents. The issue of whether the claimed microparticles of the present application would have the same properties as the compositions of the '119 or '374 patents, or the Examiner's proposed combination of these patents, is not relevant because no combination of these patents can ever teach or suggest all of the limitations of the only independent claim, claim 36, of the present application, which contains only structural limitations and does not recite any properties. In other words, since neither the '119 patent nor the '374 patent contain any teachings or suggestions whatsoever concerning the use of a norbornene-ethylene copolymer and/or tetracyclododecene-ethylene copolymer as the matrix material, the Examiner cannot, as a matter of law, establish a prima facie case of obviousness from these references. Until the Examiner can establish a prima facie case of obviousness, applicants are not required to show any secondary considerations of non-obviousness, such as unexpected results, etc.

In view of all of the above, it is respectfully submitted that the rejection of claims 20-22, 27 and 31-37 under 35 U.S.C. 103(a) as being unpatentable over the '374 patent in view of the '119 patent is incorrect and should be withdrawn.

Claims 19 and 26 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Cardarelli '374 in view of Cardarelli '119 and Kanda et al. (U.S. Patent No. 4,923,894). This rejection is respectfully traversed for the reasons set forth below.

The Examiner has acknowledged that the Kanda et al. patent does not teach the cycloolefin copolymer of the present claims. The Examiner has stated that Kanda et al. is being combined with the '374 and '119 patents and is being cited solely for the teaching of a polymeric microparticle encapsulating active substance having pesticidal activity. Without agreeing or disagreeing with the Examiner about the teachings of the Kanda et al. patent, it is respectfully submitted that this rejection is deficient for the same reasons as discussed above concerning the rejection over the combination of the '119 and '374 patents. It is respectfully submitted that the Kanda et al. patent adds no teaching which cures the deficiency in the teachings of the '119 and '374 patents relating to the cycloolefin copolymer of the present claims. Accordingly, the Examiner has not established a prima facie case of obviousness and the rejection of claims 19 and 26 as being unpatentable over the '374 patent in view of the '119 patent and Kanda et al. should be withdrawn.

Claims 23-25, 28 and 29 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Cardarelli '374 in view of Cardarelli '119 and Jacobs et al. WO 98/27125 (equivalent to U.S. Patent No. 6,365,686). This rejection is respectfully traversed for the reasons set forth below.

The Examiner has acknowledged that the '374 and '119 patents contain no teachings concerning the physical/chemical properties of the thermoplastic polymer. The Examiner then goes on to state that "products of identical chemical composition cannot have mutually exclusive properties" and cites the Jacobs patent as teaching cycloolefin copolymers such as ethylene

norbornene with a particular set of properties. The Examiner then goes on to state that it would be obvious to modify the polymer matrix of the '374 and '119 patents using the ethylene-norbornene copolymer in view of the teachings of the Jacobs patent because the '119 patent teaches the polymer matrix is made of terpolymer including copolymer of ethylene norbornene and because the Jacobs patent teaches cycloolefin copolymers are suitable for use as thermoplastic molding composition of any size and shape. According to the Examiner, the expected result would be a stable controlled release polymer matrix comprising active compounds that is useful in the agrochemical field.

It is respectfully submitted that the Examiner's combination of the '374 patent, the '119 patent and the Jacobs patent is incorrect for many reasons, two of which are discussed below.

First, the Examiner states that the '119 patent and the '374 patent are silent with respect to the physical/chemical properties of "the thermoplastic polymer". Although this is true, it must be recognized that the '119 patent does not contain any teachings at all concerning the use of thermoplastic polymers as the matrix material. The '119 patent teachings are limited to elastomers as the matrix material. Therefore, there is no reason why an artisan of ordinary skill would substitute the thermoplastic copolymers of the Jacobs patent for the elastomers of the '119 patent. As discussed above, elastomers and thermoplastics are different types of polymeric materials with different properties. According to the teachings of the '374 patent, the active compounds of the '119 patent would not be soluble in the thermoplastic ethylene norbornene copolymer of the Jacobs patent. Therefore, since solubility of the active compounds in the matrix material is a requirement of the '119 patent, it is clear that an artisan of ordinary skill would not substitute the thermoplastic ethylene norbornene copolymer of the Jacobs patent for the matrix polymers of the '119 patent.

Second, although the '374 patent at least relates to the use of thermoplastic polymers as the matrix material, the '374 patent describes hundreds if not thousands of thermoplastic polymers that are suitable for use as matrix material without ever teaching the copolymers of the present claims. Further, the '374 patent contains no teachings that could be interpreted as a suggestion to modify the matrix, much less suggest the specific modifications that would be necessary to motivate one of ordinary skill in the art to use the copolymers of the present claims. The Jacobs patent primarily teaches new methods of making cycloolefin copolymers. The patent contains general teachings concerning the usefulness of the copolymers for structural molding applications and impact resistant structural members and specific teachings concerning the usefulness of the copolymers for optical products and films. Contrary to the Examiner's conclusion, the Jacobs patent contains no teachings whatsoever that would lead to an expectation that the copolymers could be successfully used as matrix materials for the stable controlled release of active compounds in the agrochemical field. For example, it contains no teachings concerning the use of the copolymers as matrix materials for the controlled release of compounds to the environment. Further, it contains no teachings at all concerning the use of the copolymers in the agrochemical field. Accordingly, there are no teachings in the Jacobs patent that would provide any motivation to use the copolymers of that patent as the matrix material in the composition of the '374 patent and no teachings that could provide an artisan of ordinary skill with an expectation of success if the copolymers of the Jacobs patent were so used in the '374 composition. Still further, if the Examiner's position was correct, then it would be obvious to use any thermoplastic polymeric material as the matrix material in the '374 patent. However, this is not what the '374 patent teaches. Instead, the '374 patent teaches a large number of specific thermoplastic polymeric materials that are suitable for use as the matrix material. There is simply no teaching in the Jacobs patent that makes the copolymers of that patent more

desirable for use as the matrix material in the '374 patent than any other thermoplastic polymeric material disclosed in the prior art. In essence, the Examiner is simply picking and choosing among disparate references to reconstruct the invention of the present claims and then justifying the reconstruction by using the teachings of the present application itself as support. This is clearly improper. Without the teachings of the present application as a guide, there is no teaching or suggestion in the cited references that would lead one of ordinary skill to use a norbornene-ethylene copolymer and/or tetracyclododecene-ethylene copolymer as the matrix material in a controlled release composition.

In view of the above, it is respectfully submitted that the rejection of claims 23-25, 28 and 29 under 35 U.S.C. 103(a) as being unpatentable over Cardarelli '374 in view of Cardarelli '119 and Jacobs et al. is incorrect and should be withdrawn.

Claims 30 and 38 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Cardarelli '374, in view of Cardarelli '119 and Eby, III (U.S. Patent No. 5,409,905). This rejection is respectfully traversed for the reasons set forth below.

The Examiner has stated that she is citing the '374 and '119 patents for the reasons discussed above and is citing the Eby patent solely for the teaching that zinc can be used in the treatment of the common cold. Since the Examiner believes that the '374 patent teaches zinc as one of the trace nutrients that can be released by the matrix of the composition of that patent, she believes that the '374 patent teaches the use of the polymer matrix of that patent in a pharmaceutical composition. Without agreeing or disagreeing with the Examiner about the teachings of the Eby and '374 patents, it is respectfully submitted that this rejection is deficient for the same reasons as discussed above concerning the rejection over the combination of the

'119 and '374 patents. It is respectfully submitted that the Eby patent adds no teaching which cures the deficiency in the teachings of the '119 and '374 patents relating to the cycloolefin copolymer of the present claims. Accordingly, the Examiner has not established a prima facie case of obviousness and the rejection of claims 30 and 38 as being unpatentable over the '374 patent, in view of the '119 patent and Eby is incorrect and should be withdrawn.

In view of the above, applicants believe that claims 19-38 of the present application are in condition for allowance.

Applicants believe that no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 03-2775, under Order No. 09879-00017-US from which the undersigned is authorized to draw.

Respectfully submitted,

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